K070869

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JUN 15 2007

510(k) Summary
Prophy Star 3 Hygiene Handpiece
May 21, 2007

Company:

DentalEz Inc., StarDental Division
Owner/operator number 2520265

Contact Person:

William Guscott
Engineering Manager
DentalEz Inc., StarDental Division
1816 Colonial Village Lane
Lancaster, PA 17601
Phone: (717) 291-1161, ext. 4319
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Proprietary/Trade Name:

Prophy Star 3 Hygiene Handpiece

Common/Usual Name:

Dental Handpiece

Classification:

Dental handpiece and accessories (per 21 CFR 872.4200)

Predicate Device:

StarDental Prophy Star II Hygiene Handpiece
Micro Motors PHP 100 Prophy Handpiece (K896877)

Device Description/Intended Use:

The Prophy Star 3 Hygiene Handpiece is a low speed, pneumatically driven, hand-held device intended for use by trained dental professionals for performing dental prophylaxis. The handpiece uses either an ISO standard Doriot style reusable Prophy angle or a ISO standard Doriot style disposable angle. The Prophy Star 3 Hygiene Handpiece is a Lube Free handpiece requiring no lubrication.

Substantial Equivalence:

The determination of substantial equivalence is based on the premise that the proposed device and the predicate devices have the same intended use, similar technology and design. Both devices have the same means of operation and are used for the same procedures. Improvements made to the proposed device were initiated to improve the handpiece performance while maintaining the safety of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. William Guscott
Engineering Manager
DentalEZ, Incorporated
StarDental Division
1816 Colonial Village Lane
Lancaster, Pennsylvania 17601

JUN 15 2007

Re: K070869
Trade/Device Name: Prophy Star 3 Hygiene Handpiece
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: May 30, 2007
Received: May 31, 2007

Dear Mr. Guscott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070869

Device Name: Prophy Star 3 Hygiene Handpiece

Indications for Use:

The prophy handpiece is used by trained dental professionals to perform dental prophylaxis.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...ion Sign-Off)
...ision of Anesthesiology, General Hospital,
...ection Control, Dental Devices

...(k) Number: K070869